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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,992	11/13/2001	Terry B.J. Kuo	JCLA8137	3468

7590
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12/01/2003

EXAMINER

MACHUGA, JOSEPH S

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

CS

Office Action Summary	Application No. 09/990,992	Applicant(s) KUO, TERRY B.J.	
	Examiner Joseph S. Machuga	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2&3</u> | 6) <input type="checkbox"/> Other: |

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hearing instrument as recited in claims 3 and 10 and the personal computer, PDA and microchip recited in claims 5 and 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4-7, 9-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor #5301679 in view of Kuo et al (Effect of Aging on Gender Difference in Neural Control of Heart publication.)

Taylor discloses method and apparatus for analyzing heart sounds. The device includes a microphone (1), amplifier (3), filters (7) and a personal computer (10.) The device looks for abnormalities in the heart sound. As noted in column 5, lines 61-68 abnormal sounds such as third heart sound, fourth heart sound, systolic and diastolic murmurs,

systolic ejection click, and variations in amplitude and frequency are abnormal sounds that can be associated with cardiac disease. Not disclosed by this reference is the analysis of the HRV value.

Kuo et al disclose a method of analyzing ECG heart data. The method includes looking at the HRV factors. Included in the document (see column 3, section entitled "Processing of ECG signals") is a method of analyzing this data that includes measuring the amplitude and duration; calculating the means and standard deviation; comparing the amplitude and duration with a standard template and rejecting the spike signals that exceed 3X the standard template. The reference also teaches estimating the beat-to-beat intervals. The analysis provides an indication of the sympathetic/parasympathetic balance and is commonly used as an indicator of a patients health.

Given this teaching, it would have been obvious to one of ordinary skill in the art to modify Taylor's medical device to analyze the HRV parameters as discussed in Kuo et al's document to provide a diagnostic tool that looks at these factors.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Kuo et al as applied to claim 1 above, and further in view of either Eisenburg et al or Johnson et al.

Both Eisenburg and Johnson et al teach integrating the electronics of a heart analyzer into a stethoscope (instrument used in auscultation.) The devices would obviously add convenience to the practitioners.

Given there teaching it would have been obvious to one of ordinary skill in the art to incorporate the analyzer of the proposed combination into a stethoscope to add convenience for the practitioner.

Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Kuo et al as applied to claims 1, 2, 4-7, 9-14 and 16 above, and further in view of Tsuji et al (The Framingham Heart Study.)

Tsuji et al teach analyzing the HRV data that includes in addition to LF, HF, LF/HF the TP value to predict the outcome of a patient.


Given this teaching it would have been obvious to one of ordinary skill in the art to include the total power (TP) value in the analysis of the heart data in the proposed combination to provide an indicator of the hearts strength.

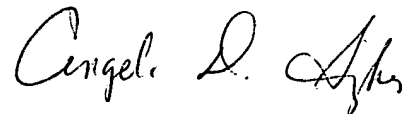
5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.


Joseph S. Machuga
Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700